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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,976	09/29/2003	Mark Van Dyke	SwRI-2921-04	2598

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EXAMINER

WAX, ROBERT A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,976	VAN DYKE, MARK	
	Examiner	Art Unit	
	Robert A. Wax	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-114 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-114 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4 of them</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed November 6, 2003, February 24, 2004, March 2, 2004 and March 8, 2004 have been considered. Please see the attached initialed PTO-1449s.

Claim Rejections - 35 USC § 112, Second Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-18, 44, 45, 50, 55, 56, 63-74, 78-80, 94, 98-103 and 112-114 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 11 and 13, the phrases, "adapted to covalently bond with sulfur" and "adapted to be displaced from R by a sulfur anion" are not understood. How exactly are R and X, respectively, adapted?

In claims 12 and 14, the phrase, "reacts with the crosslinking agent" makes no sense. How can R react with the crosslinking agent when it is itself the crosslinking agent?

In claims 44 and 50, the term "phthallic" is misspelled; it should read, "phthalic."

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In claim 94, there is no definition of R³ or R⁴.

In claims 98, 100 and 102 there is no definition of R⁵.

In claim 112, the phrase "said α -keratins" lacks antecedent basis in claim 111.

In claims 113 and 114, the phrase, "said cross-linked keratin network" lacks antecedent basis in claims 111 and 112, respectively.

Claims 15-18, 45, 95, 99, 101 and 103 are included in this rejection because they do not cure the defect for which the claims from which they depend are rejected.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 75 and 76 are rejected under 35 U.S.C. 102(e) as being anticipated by Sojomihardjo et al.

Sojomihardjo et al. teach networks of modified peptides (column 8, line 51) comprising proteins crosslinked with moieties comprising an unsaturated group. Many

proteins are listed at column 8, lines 17-36 including collagen at line 22 (this teaching relates specifically to claim 76). These teachings thus anticipate the above claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claim 111 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al.

The general teaching of Sojomihardjo et al. is outlined above. They also teach how to regulate the properties of the gels obtained at column 8, line 52 – column 9, line 2. Attention is especially drawn to column 8, line 64, which discusses the degradation rate of the network. Clearly, the degradation is by dissolution. It would have been obvious to one of ordinary skill in the art at the time the invention was made to follow the teaching of Sojomihardjo et al. to vary the degree of crosslinking with the expectation of regulating the rate of dissolution of the crosslinked protein network by doing so.

8. Claims 1-10, 75-89 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of Timmons et al. (US Patent 6,110,487).

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The teachings of Sojomihardjo et al. have been outlined above. Vinyl as the reactive group is specifically mentioned at column 5 lines 60-63.

Timmons et al. teach methods of making materials from keratin which include modification of the keratin by reduction of the disulfide linkages to thiol groups which are used as the sites for crosslinking later, see column 14, lines 5-9. Glutaraldehyde is mentioned specifically as the crosslinking agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to practice the invention of crosslinking protein with crosslinking agents comprising unsaturated groups such as vinyl groups taught by Sojomihardjo et al. with keratin instead of collagen in view of the teachings of Timmons et al. of keratin's lack of antigenicity conferring biocompatibility at column 3, lines 43-53. With regard to claims 113 and 114, it would have been obvious to alter the solubility characteristics of the network to whatever value is desired in accordance with the teachings of Sojomihardjo et al. as discussed above in the rejection of claim 111. The limitation of claim 112 is taught by Timmons et al. at column 6, lines 45-49, for example. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

With regard to claims 9 and 10, attention is directed to Timmons et al. at column 5, lines 31-35 where they state that the keratin is provided in solution with thioglycolate and, therefore, has free thiol groups. These thiol groups will be in the thiolate form at acidic pH. One of ordinary skill in the art would have found it obvious to prepare the keratin according to this teaching of Timmons et al. and change the disulfide bridges to

free thiolate as the first step of crosslinking according to the process of Sojomihardjo et al. with the expectation of beneficial results.

9. Claim 90 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of Perrier et al.

The teachings of Sojomihardjo et al. have been outlined above. In addition, Sojomihardjo et al. teach many applications of crosslinked protein gels including encapsulation of biologically active materials.

Perrier et al. teach crosslinking proteins such as elastin, keratin or collagen (see column 3, lines 13-22) with acid anhydrides or polybasic carboxylic acid (see column 4, lines 5-12). The crosslinked proteins of Perrier et al. are used to make microcapsules or nanocapsules.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the polybasic acid or anhydride taught by Perrier et al. as the crosslinking agent while practicing the invention of Sojomihardjo et al. because they are taught as equivalents and one of ordinary skill would expect a useful crosslinked polymer network to result.

10. Claims 40-45, 50 and 90-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of Perrier et al. and Timmons et al. (US Patent 6,110,487).

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The teachings of Sojomihardjo et al. have been outlined above. In addition, Sojomihardjo et al. teach many applications of crosslinked protein gels including encapsulation of biologically active materials.

Perrier et al. teach crosslinking proteins such as elastin, keratin or collagen (see column 3, lines 13-22) with acid anhydrides or polybasic carboxylic acid (see column 4, lines 5-12). The crosslinked proteins of Perrier et al. are used to make microcapsules or nanocapsules.

The teachings of Timmons et al. are outlined above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sojomihardjo et al. and Perrier et al. since they are clearly analogous art and represent variations on a theme. Such combined teachings would render it obvious to use keratin or elastin instead of the collagen taught by Sojomihardjo et al. with the expectation that beneficial results would be obtained. It further would have been obvious to substitute the unsaturated crosslinking agent of Sojomihardjo et al. with the acid or acid anhydride of Perrier et al. similarly expecting beneficial results. Further motivation to use keratin as the protein is provided by Timmons et al. who teach the many benefits attained by using keratin including lack of antigenicity conferring biocompatibility at column 3, lines 43-53. When the specific crosslinker, terephthaloyl chloride, is used (column 4, line 9 of Perrier et al.), the crosslinker recited in claims 94 and 95 is obtained when they react with the cysteines in the keratin. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

11. Claims 46-49, 53-74 and 98-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of Perrier et al. and Timmons et al. (US Patent 6,110,487) as applied to claims 40-45, 50 and 90-95 above, and further in view of Jiang et al.

The teachings of Sojomihardjo et al., Perrier et al. and Timmons et al. have been outlined above.

Jiang et al. teach that hexamethylene diisocyanate and dihalo isocyanates cyanate esters are known crosslinking agents for polymers at column 2, lines 9-26:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the diisocyanates of Jiang et al. as the crosslinking agent in place of the anhydride or polyacid of Perrier et al. expecting beneficial results in view of interchangeability of crosslinking agents taught by Jiang et al. With regard to claims 63-67, Sojomihardjo et al. teach covalent bonds, thus rendering these claims obvious as well. With regard to claims 68-74, Timmons et al. teach thiol as the reactive pendant group, thus rendering these claims obvious. When one of the diisocyanates of Jiang et al. are used as the crosslinking agent, the structure recited in claims 98 and 99 is obtained when they react with the serines in the keratin. When one of the diisocyanates of Jiang et al. are used as the crosslinking agent, the structure recited in claims 100 and 101 is obtained when they react with the cysteines in the keratin. When one of the diisocyanates of Jiang et al. are used as the crosslinking agent, the structure recited in claims 102 and 103 is obtained when they react with the arginines in the keratin. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

12. Claims 9-18, 53-62 and 104-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of O'Lenick, Jr. and Timmons et al. (US Patent 6,110,487).

The teachings of Sojomihardjo et al. and Timmons et al. have been outlined above.

O'Lenick Jr. teaches crosslinking proteins such as keratin and collagen (see column 6, lines 57-58) with polyoxyalkylene compounds.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sojomihardjo et al. and O'Lenick Jr. since they are clearly analogous art and represent variations on a theme. Such combined teachings would render it obvious to use keratin or elastin instead of the collagen taught by Sojomihardjo et al. with the expectation that beneficial results would be obtained. It further would have been obvious to substitute the unsaturated crosslinking agent of Sojomihardjo et al. with the polyoxyalkylene compounds of O'Lenick Jr. similarly expecting beneficial results. Further motivation to use keratin as the protein is provided by Timmons et al. who teach the many benefits attained by using keratin including lack of antigenicity conferring biocompatibility at column 3, lines 43-53. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

With regard to claims 9-18, one of ordinary skill in the art would also have found it obvious to use the polyoxyalkylene groups of O'Lenick, Jr. in the method of claim 9 for the same reasons outlined in the previous paragraph.

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13. Claims 19-39 and 108-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of O'Lenick, Jr. and Timmons et al. (US Patent 6,110,487) as applied to claims 9-18, 53-62 and 104-107 above, and further in view of Margolin et al. and Nagase Chemtex.

The teachings of Sojomihardjo et al., O'Lenick, Jr. and Timmons et al. have been outlined above.

Margolin et al. teach crosslinking proteins with epoxides. This is discussed specifically at column 16, line 32-58. Epichlorohydrin is mentioned as a reactant at column 16, lines 33-39. In addition, they use products called DENACOL, which are defined, further on the technical data sheet from Nagase Chemtex as various epoxides.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the polyoxyalkylene compounds of O'Lenick Jr. with the epoxides taught by Margolin et al. and Nagase Chemtex similarly expecting beneficial results. When the epoxides of Margolin et al. are used as the crosslinking agent, the structure recited in claims 95 and 96 is obtained when they react with the cysteines in the keratin and the structure recited in claim 97 comes from the reaction with cysteine on one side and arginine on the other. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

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14. Claims 51, 52, 96 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sojomihardjo et al. in view of Jiang et al. (US Patent 5,505,952) and Timmons et al. (US Patent 6,110,487).

The teachings of Sojomihardjo et al. and Timmons et al. have been outlined above.

Jiang et al. teach crosslinking polyamino acids using, as the crosslinking agent, diamines (see column 2, line 25). They teach that the crosslinking agent reacts with amino acids which have pendant groups including carboxyl groups, see column 2, lines 59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Sojomihardjo et al. and Jiang et al. since they are clearly analogous art and represent variations on a theme. Such combined teachings would render it obvious to substitute the unsaturated crosslinking agent of Sojomihardjo et al. with the amine of Jiang et al. similarly expecting beneficial results. It would further have been obvious to use keratin as taught by Blanchard et al. instead of the collagen taught by Sojomihardjo et al. for the reasons outlined by Timmons et al. When an amine as taught by Jiang et al. is used as the crosslinker, the structure recited in claims 96 and 97 is obtained when the amine reacts with the amino acids having a carboxylic side chain (glutamic and aspartic acids) in the keratin. Sojomihardjo et al. clearly teach that variation of the degree of substitution is one way of varying the properties of the resultant gel, from soft gel to microcapsule and anywhere in between. Thus, the invention defined by the above claims would have been obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 75-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 10, 14, 16, 20, 22, 28, 33, 38, 46, 53, 60, 71, 72, 79, 80, 153 and 160 of copending Application No. 10/411,358 in view of Blanchard et al. (US Patent 6,379,690).

The instant claims are directed to crosslinked keratin networks whereas the claims in copending application 10/411,358 are drawn to wound dressings. Blanchard et al. (US Patent 6,379,690) teach crosslinked keratin networks used as wound dressings, thus, the instant claims are claiming an obvious variation of the claims of copending application 10/411,358. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 75-114 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/411,358 in view of Blanchard et al. (US Patent 6,379,690) and Jiang et al.

The instant claims are directed to crosslinked keratin networks whereas the claims in copending application 10/411,358 are drawn to wound dressings. Blanchard et al. (US Patent 6,379,690) teach crosslinked keratin networks used as wound dressings. Jiang et al. teach crosslinked polypeptides for use as wound healing agents and, at column 3, line 65 - column 4, line 21, they teach that therapeutic agents may be incorporated into the crosslinked polypeptide. Thus, the instant claims are claiming an obvious variation of the claim of copending application 10/411,358. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Wax whose telephone number is (571) 272-0623. The examiner can normally be reached on Monday through Friday, between 9:00 AM and 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Robert A. Wax', is positioned above the printed name and title.

Robert A. Wax
Primary Examiner
Art Unit 1653

RAW.